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Attachment 12

MICOMED – HALM ZIELKE INSTRUMENTATION SYSTEM
510(K) SUMMARY

Tradename:	Micomed Halm Zielke Instrumentation System
Generic Name:	Spinal Intervertebral Body Fixation Orthosis
Classification:	Class II (21 CFR 3060)
Company:	Micomed Ortho GmbH & Co. KG Schorndorfer Strasse 96 Schorndorf 73614 Germany Phone: 011 49 71 81 48 99 85 87 Fax: 011 49 71 81 48 99 84 info@micomed.com
Contact:	Corrine M. Bonfiglio, RAC Tel: (858) 342-0344 Fax: (858) 481-2363 cbonfiglio@meister.net
Predicate Devices:	Micomed Halm Zielke Instrumentation System, 510(k) #K982006 Zielke V.D.S. System, 510(k) #K782061 DePuy AcroMed MOSS Miami Spinal System, 510(k) #K983583 Kaneda Anterior Scoliosis System, 510(k) #K974757
Description:	The principal components of the Micomed Halm Zielke Instrumentation System, which is a low profile spinal fixation system, are as follows: Halm and HC plates, screws, threaded rods, standard hex nuts for threaded rods, fluted rods, and vertebral clamps (double and single hole). Additional instrumentation includes: awls, wrenches, insertion instruments for rods and screws, vertebral and end vertebra screws, top loading screws and set screws, rod pushers and rod benders, grip and compression tongs, rod cutter and distraction instrument. The principal components of the Micomed Halm Zielke Instrumentation are used in the following manner: First, the most cranial and caudal Halm plates are each attached to the lateral aspect of the vertebral body with two screws (countersunk, Zielke), and then additional plates are attached as needed. The threaded rod is then connected to the top of the Zielke screws and anchored with the standard hex nuts. Once the threaded rod is properly connected to the Halm plates, partial correction of the scoliotic deformity is performed before attaching the pre-bent fluted rod by closing the lid of the Halm plate and securing with the head screws. The secured fluted rod can then be rotated around its longitudinal axis to achieve and appropriate level of derotation and relordosation. If this system is used in the thoracic spine, rod rotation is performed in reverse to produce or enhance physiological kyphosis. Additionally, segmental compression or distraction can be used to increase or decrease lordosis or kyphosis, as desired.

	510(k) Summary - continued
Material:	The components of the Micomed Halm Zielke Instrumentation are manufactured from implant grade titanium (Ti 6AL 4V) conforming to ASTM F136 or implant grade stainless steel (316 LS) conforming to ASTM F1314 specifications.
Indications:	The Halm Zielke Instrumentation System is an anterior spinal fixation system indicated for spinal deformities in the thoracic and lumbar spine such as scoliosis, kyphosis, and lordosis and thoracolumbar spinal instability caused by fracture.
Performance:	Testing was conducted per ASTM F1717-96. The new components have been shown to have acceptable biomechanical performance and to function in an equivalent manner to the predicated device.
Substantial Equivalence:	The new components for the Micomed Halm Zielke Instrumentation System are substantially equivalent in function, performance and intended use to the predicate Halm Zielke instrumentation cleared for market entry under 510(k) #K982006 on January 20, 1999; the Zielke V.D.S System cleared for market entry on March 21, 1979; the DePuy AcroMed MOSS Miami Spinal System, cleared for market entry under 510(k) #K983583 on December 3, 1998; and the Kaneda Anterior Scoliosis System (KASS), cleared for market entry under 510(k) #K974757, on March 5, 1998.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2003

Micromed Ortho GmbH & Co. KG
c/o Ms. Corrine M. Bonfiglio, RAC
13195 Seagrove Street
San Diego, California 92130

Re: K024125
Trade/Device Name: Halm Zielke Instrumentation System
Regulatory Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: August 7, 2003
Received: August 11, 2003

Dear Ms. Bonfiglio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 11

Statement of Indication for Use

510(k) Number: K024125

Device Name: Micomed Halm Zielke Instrumentation System

Indications for Use:

The Halm Zielke Instrumentation System is an anterior spinal fixation system indicated for spinal deformities in the thoracic and lumbar spine such as scoliosis, kyphosis, lordosis and thoracolumbar spinal instability caused by fracture.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K024125

Prescription Use _____ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)